MEDICAL INSTRUMENT

TECHNICAL FIELD

[0001] The present invention relates to a medical instrument (a catheter device) that cuts deposits from a narrowed coronary artery or other vascular site with a rotating cutter means to establish patency of a passageway through the vascular site or to distend the narrowed vessel.

BACKGROUND ART

[0002] To treat a disease caused by deposits on the wall of a blood vessel, it is customary to insert a catheter device into a patient's body down to an intravascular treatment site to remove the deposits or to distend the narrowed vessel.

[0003] Fig. 17 is a schematic diagram explanatory of a procedure for scraping deposits off the wall of a blood vessel.

[0004] The first thing to do is to insert a small-diameter guide wire 105 into a blood vessel 101 and navigate it past a narrowed vascular site 107, followed by inserting a small-diameter catheter device 125 into the vessel along the guide wire 105. The catheter device 125 has a grindstone 127 (similar to cutting bars 60 and 70 described later on) and a drive shaft 129 formed by a coiled wire. The next step is to drive the grindstone 127 of the catheter device 125 at high speed (approximately 200,000 rpm, for instance) to grind away deposits 103 to broaden first the entrance of the narrowed vascular site 107 up to a diameter of around 1 mm for ease in centering the grindstone 127, which is then inserted in its entirety through the narrowed vascular portion.

[0005] Following this, the catheter device 125 is pulled out of the vessel, with the guide wire 105 left remaining therein intact, and another catheter device with a slightly larger-diameter grindstone is inserted into the vessel along the guide wire and is driven to scrape the deposits 103 in the same manner as mentioned above. This operation is repeated using catheter devices that are replaced one after another in ascending order of diameters of the grindstone and the guide wire to gradually enlarge the diameter of the narrowed vascular portion 107 up to an ultimate value of approximately 2.5 mm.

[0006] As described above, the conventional medical instrument for this kind of treatment

employs what is called a rotor ablator. That is, a rotary cutting bar (a rotating grindstone) is rotatably and slidably mounted on the guide wire that is inserted through a narrowed portion of a coronary artery, and the rotary cutting bar is rotated at high speed to perform treatment of the narrowed portion of the coronary artery by the removal of the calcified deposits on the vessel wall.

[0007] Turning next to Figs. 15 and 16, a particular example of the cutting bar (the aforementioned grindstone 127) will be described below.

[0008] Fig. 15 is a partially sectioned side view showing the cutting bar of the conventional medical instrument in association with a narrowed vascular portion.

[0009] The cutting bar 60 is driven for rotation at high speed about a guide wire (not shown). The cutting surface of the cutting bar 60 is coated with diamond abrasive grains 61. The diamond abrasive grains 61 greatly differ in grain size, and the cutting surface is covered with a plated layer 62.

[0010] Such a cutting bar 60 can be used as a device that enables effective treatment for removing calcified deposits from the narrowed coronary artery or similar vascular portion. In this instance, the cutting force to the narrowed vascular portion 2 and the size of chippings correspond to the force of urging the cutting bar 60 against the narrowed vascular portion 2.

[0011] Fig. 16 shows in section, different cutting bar structures of conventional medical instruments.

[0012] In the case of a cutting bar 70 of Fig. 16(A), cutting edges 71 of conventional sizes are formed in the cutting surface in place of the diamond abrasive grains 61 shown in Fig. 15. With the cutting bar having such cutting edges 71 formed in the cutting surface, too, it is possible to remove deposits of the narrowed vascular portion 2.

[0013] Because of such configurations of the prior art treatment device, in the case of the cutting bar 60 of Fig. 15, there is a fear that during removal of deposits from the narrowed vascular portion 2 the diamond abrasive grains 61 fall off due to a cutting reaction force from the calcified hard deposits and flow downstream in the vessel, sometimes blocking peripheral

vessels. Besides, chippings of the diamond abrasive grains 61 vary in size with the force for pressing the cutting surface against the deposits and with the cutting speed; this gives rise to a problem that when the cutting surface is urged against the deposits quickly and firmly, chippings may sometimes become large and are likely to occlude peripheral vessels.

[0014] On the other hand, in the case of the cutting bar 70 of Fig. 16, when the cutting bar 70 itself is pressed axially thereof for plastic deformation in a direction to increase its diameter, the cutting edges 71 may crack or deform as indicated by 72 in Fig. 16(B), resulting in a significant reduction in cutting performance.

[0015] The cutting bars 60 and 70 both have a rigid structure with a grinding surface coated with abrasive grains, and have no mechanism for increasing the diameter of the cutting surface portion. Accordingly, in a case where it is desirable to distend the calcified narrowed vascular portion to a diameter larger than that of an initially distended vascular lumen, the rotating cutting bar (the grindstone 127 in Fig. 17) needs to be replaced with a cutter of larger diameter after being completely pulled in its entirety off the guide wire (105), together with the drive shaft (129). In nearly 40% of past cases, two large- and small-diameter versions were used for each of the rotary cutting bar (the grindstone 127) and the drive shaft (129) (an average number used per case being 1.4), and they needed complicated replacement work in a clean region in an operating room.

[0016] In this respect, since the conventional rotary cutting bars 60 and 70 are both held unitary with the drive shaft, their replacement is required to follow the below-listed steps 1 to7, and hence it is complicated.

[0017] The procedure for replacement comprises the steps of:

1. Disengaging the drive shaft (129 in Fig. 17) from a drive control assembly;
2. Pulling the drive control assembly off the guide wire;
3. Pulling the rotary cutting bar and the drive shaft (grindstone 127 and drive shaft 129) out of a patient's body in their entirety and then pulling them off the guide wire, too;
4. Putting a rotary cutting bar and a drive shaft (grindstone 127 and drive shaft 129), both larger in diameter, on the guide wire;
5. Navigating the rotary cutting bar (grindstone 127) to a treatment site in a coronary

artery of a patient;

6. Putting the drive control assembly on the guide wire; and

7. Operatively connecting the drive control assembly to the larger-diameter rotary cutting bar and drive shaft (grindstone 127 and drive shaft 129).

[0018] In view of the above-mentioned problems, the present invention has for its object to provide a medical instrument that, in the case of distending a narrowed vascular lumen after initial treatment, permits enlarging the diameter of the rotating cutter on the guide wire left remaining in the blood vessel, without the need for pulling the rotating cutter off the guide wire.

[0019] Another object of the present invention is to provide a medical instrument that allows ease in enlarging the diameter of the rotating cutter on the guide wire after once pulling the rotating cutter out of a patient's body along the guide wire left remaining in the blood vessel.

[0020] Still another object of the present invention is to provide a medical instrument that permits quick and effective removal of an intravascular narrowing material by a rotating cutter.

DISCLOSURE OF THE INVENTION

[0021] To solve the above-described problems, a medical instrument according to a first embodiment of the present invention comprises:

a guide wire that is inserted at one end through a vascular lumen narrowed by deposits and is extended at the other end out of a patient's body;

a rotating cutter that is rotatably and slidably guided over the guide wire and is driven to cut away the deposits in said narrowed vascular lumen;

a hollow drive shaft that is operatively connected to the rotating cutter and through which the guide wire is inserted;

a fixed sheath having inserted therein the drive shaft; and

a controller having a drive assembly for rotating the drive shaft;

wherein the rotating cutter is driven to perform intravascular treatment to establish patency of said narrowed vascular lumen or to distend the vascular lumen;

wherein:

the rotating cutter contains on its surface a plurality of independent microscopic cutting edges formed integrally with a mother material of the cutter.

[0022] The medical instrument according to the first embodiment of the present invention is adapted such that the rotating cutter can be compressed axially thereof for plastic deformation in a direction in which to enlarge the diameter of the cutter in the case of further distending the narrowed vascular portion after removal therefrom of deposits by the cutter.

[0023] In this case, a cutting reaction force which is applied to the surface of the rotating cutter during removal of the vascular narrowing material is reduced . This permits reduction of the thickness of the rotating cutter, precluding the possibility of cracking or deformation of the microscopic cutting edges by plastic deformation of the rotating cutter for enlargement of its diameter thereby suppressing reduction in the cutting performance.

[0024] A medical instrument according to a second embodiment of the present invention comprises:

a guide wire that is inserted at one end through a vascular lumen narrowed by deposits and is extended at the other end out of a patient's body;

a rotating cutter that is rotatably and slidably guided over the guide wire and is driven to cut away the deposits in the narrowed vascular lumen;

a hollow drive shaft that is operatively connected to the rotating cutter and through which the guide wire is inserted;

a fixed sheath having inserted therein the drive shaft;

a controller having a drive assembly for rotating the drive shaft; and

a secondary treatment rotating cutter whose cutting surface has an outside diameter larger than the maximum outside diameter of the cutting surface of the rotating cutter (an initial treatment rotating cutter);

wherein:

the initial treatment rotating cutter and the secondary treatment rotating cutter contain on their surfaces great numbers of independent microscopic cutting edges formed integrally with mother materials of the cutters; and

in the case of further distending the narrowed vascular portion after cutting treatment of the narrowed vascular portion by the initial treatment rotating cutter, the secondary treatment rotating cutter is coupled to the initial treatment rotating cutter on that portion of the guide wire extending out of the patient's body in such a manner that the cutting edges of both of the rotating

cutters are sufficiently closely and appropriately spaced apart in a direction in which to remove deposits from the narrowed vascular portion.

[0025] In the medical instrument of the present invention, the microscopic cutting edges are microscopic asperities formed on the peripheral surfaces of said cutters, and the heights, depths, widths and lengths of the asperities are chosen such that chippings of the deposits cut by the cutters are 10 microns or below in size.

[0026] This could preclude the possibility of occlusion of peripheral blood vessels by chippings removed from the narrowed vascular portion.

[0027] In the medical instrument of the present invention, the asperities have elongated grooves that extend in the direction of rotation of the cutter, get gradually deeper toward rearwardly in the direction of rotation of the cutter and terminate at the deepest point at which the grooves rise steeply, and protrusive cutting edges that extend upright from the deepest point of the grooves and jut out of the cutter surface.

[0028] In the medical instrument of the present invention, the microscopic cutting edges are formed on the mother material surface of each cutter by laser machining, electric discharge machining, chemical etching, press work, pressure welding, or cutting work.

[0029] In this case, the microscopic cutting edges can be formed with ease.

[0030] In the medical instrument of the present invention, cutting surface forming areas of the plurality of microscopic asperities forming the microscopic cutting edges are disposed in overlapping relation with one another.

[0031] In this case, it is possible to form a cutting surface configuration in which the respective microscopic cutting edges are individually independent and densely packed. This reduces the amount of deposits left unremoved in the narrowed vascular portion.

[0032] In the medical instrument of the present invention, the plurality of microscopic asperities forming the microscopic cutting edges are composed of asperities whose cutting surfaces oriented in a normal direction of rotation of the cutter and asperities whose cutting surfaces oriented in a direction opposite to the normal direction of rotation of the cutter.

[0033] In this case, the cutting force of the cutter can be changed by switching between the one and the other direction of rotation of the cutter. This makes it possible to perform cutting treatment according to the condition of the affected area.

[0034] In the medical instrument of the present invention, the cutter surface can be a mirror-finished surface.

[0035] Alternatively, the cutter surface can be coated with a plated layer.

[0036] In these cases, it is possible to suppress generation of frictional heat between the rotating cutter and the affected area.

[0037] In the medical instrument of the present invention can be adapted such that the rotating cutter is adapted to be compressed axially by a jig preplaced coaxially with or in proximity to the drive shaft to undergo plastic deformation in a radial direction in which to enlarge the diameter of the rotating cutter.

[0038] In the medical instrument of the present invention, the secondary treatment rotating cutter can be adapted to be press-fitted, by a jig preplaced coaxially with or in proximity to the drive shaft, into or onto the initial treatment rotating cutter for engagement therewith.

[0039] In the medical instrument of the present invention, the jig can have a one-hand operated, squeeze-type lever mechanism utilizing a force-multiplying mechanism by a lever or cam.

[0040] In this case, the initial treatment rotating cutter and the secondary treatment rotating cutter can easily be joined together.

[0041] In the medial instrument of the present invention, the controller can have a mechanism for pushing the rotating cutter out forwardly from a distal end of the fixed sheath toward the affected area and a mechanism for retracting the rotating cutter, and these mechanisms can be actuated by a squeeze-type operating lever provided with an auto-return mechanism and a position retaining mechanism.

[0042] In this case, the rotating cutter can easily be pushed out forwardly from a distal end of the fixed sheath toward the affected area or retracting the rotating cutter.

[0043] In the medical instrument of the present invention, the controller is provided with a vibrating mechanism for reciprocating the rotating cutter on the guide wire.

[0044] In this case, since combined cutting forces by rotary and reciprocating motions can be imparted to the rotating cutter, it is possible to increase or stabilize the cutting force of the rotating cutter for removing deposits from the narrowed vascular portion. Furthermore, the rotating cutter and the fixed sheath can easily be inserted into the guiding catheter with reduced friction.

[0045] In the present invention, the controller can have built therein a drive assembly for rotating the drive shaft, and the drive assembly can have a motor provided with a hollow rotary shaft through which the drive shaft is insertable.

[0046] Such an arrangement eliminates the need for pulling off the drive shaft in its entirety from the guide wire, allowing ease in pulling the drive shaft out of the patient's body along the guide wire left remaining within the body.

[0047] In the present invention, the controller can be provided with a drive shaft chucking mechanism and a soft-sheath attaching/detaching mechanism.

[0048] The chucking mechanism ensures transmission of motor driving force to the drive shaft. Moreover, the chucking mechanism allows ease in detaching the sheath from the controller in the case of performing interior maintenance of the controller.

BRIEF DESCRIPTION OF THE DRAWINGS

[0049] Fig. 1 is a perspective view explanatory of the usage pattern of a medical instrument according to a first embodiment of the present invention.

[0050] Fig. 2 is a perspective view showing, on an enlarged scale, a controller of the medical instrument of fig. 1.

[0051] Fig. 3 is a partially broken-away perspective view showing the controller of Fig. 2.

[0052] Fig. 4 is a perspective view illustrating a rotating cutter of the medical instrument according to the first embodiment of the present invention.

[0053] Fig. 5 is a radially sectioned elevational view partially showing the cutting surface of the rotating cutter of Fig. 4.

[0054] Fig. 6 is an axially sectioned elevational view of Fig. 5.

[0055] Fig. 7(A) is a perspective view showing an initial treatment rotating cutter and a secondary treatment rotating cutter in their yet-to-be coupled state, and Fig. 7(B) a perspective view showing the both cutters of Fig. 7(A) in their coupled configuration.

[0056] Fig. 8 is a sectional view showing a part of a rotating cutter of a medical instrument according to a second embodiment of the present invention.

[0057] Fig. 9 is explanatory of an example of forming microscopic cutting edges of the rotating cutter of the medical instrument according to the present invention.

[0058] Fig. 10 shows, partly in section, the construction of the cutting portion of a rotating cutter of a medical instrument according to a fourth embodiment of the present invention.

[0059] Fig. 11 shows, in partially sectioned side elevation, a jig for enlarging the diameter of a rotating cutter of a medical instrument according to a fifth embodiment of the present invention.

[0060] Fig. 12 is a sectioned side elevational view showing the construction of a controller of a medical instrument according to a sixth embodiment of the present invention.

[0061] Fig. 13 is a sectioned side elevational view showing, on an enlarged scale, the construction of the principal part of the controller of the medical instrument depicted in Fig. 12.

[0062] Fig. 14 is a sectioned side elevational view showing the controller of the Fig. 12 medical instrument, with a sheath connector taken away.

[0063] Fig. 15 is a partial sectional view showing a cutting bar of a conventional medical instrument in association with a narrowed vascular portion.

[0064] Fig. 16 shows, in section, different cutting structures of cutting bars of the conventional medical instrument.

[0065] Fig. 17 is a schematic diagram for explaining how to scrape off deposits.

BEST MODE FOR CARRYING OUT THE INVENTION

[0066] With reference to the accompanying drawings, the present invention will hereinafter be described.

[0067] Fig. 1 is a perspective view explanatory of the usage pattern of the medical instrument according to the first embodiment of the present invention.

[0068] At the lower left of Fig. 1 there is shown a narrowed vascular lumen 2 that needs treatment. In the illustrated state a distal end portion of the medical instrument is inserted through the narrowed vascular lumen 2.

[0069] This medication instrument has a guide wire 1. The guide wire 1 is passed at one end through the narrowed vascular portion 2 and extended at the other end out of a patient's body. On the guide wire 1 a rotating cutter (an initial treatment rotating cutter) 3 is mounted. The initial treatment rotating cutter rotates about the guide wire 1, and it is slidable over the wire 1. The rotating cutter 3 will be described in detail later on.

[0070] The rotating cutter 3 is affixed at a proximal end to a drive shaft 4. The drive shaft 4 is a hollow member made of a soft and flexible material. The drive shaft 4 is slidably inserted through a fixed sheath 5 that is a flexible cover tube. The fixed sheath 5 is inserted through a guiding catheter 6. The guiding catheter 6 is connected at a proximal end to a controller 10. The controller 10 has built therein a drive mechanism for rotating and reciprocating the drive shaft 4 at high speed.

[0071] Turning next to Figs. 2 and 3, the controller 10 will be described in detail.

[0072] Fig. 2 is an enlarged perspective view illustrating the controller of the medical instrument depicted in Fig. 1.

[0073] Fig. 3 is a partially broken-away, sectioned perspective view of the controller shown in Fig. 2.

[0074] As shown in Figs. 2 and 3, the controller 10 is provided with a rotating cutter (a

secondary treatment rotating cutter) 7. The rotating cutter 7 is one that is different from the afore-mentioned initial treatment rotating cutter 3. The treatment rotating cutter 7 has a larger cutting surface diameter than the maximum outside diameter of the cutting surface of the initial treatment rotating cutter 3. The secondary treatment rotating cutter 7 is rotatably and slidably held on that section of the drive shaft 4 which is extended out of a patient's body. The rotating cutter 7 is releasably seated in a cutter receiving concavity 12 made in a front wall of a housing 11 of the controller 10.

[0075] To the front end of the housing 11 of the controller 10 there is slidably attached a jig 13. The jig 13 is one that interengages the initial treatment rotating cutter 3 and the secondary treatment rotating cutter 7 into a one-piece structure. The jig 13 has at its front extremity a tab 13a bent upward. The tab 13a is bent upward from the marginal edge of the front end portion of the jig 13 (which extends forwardly of the front end face of the housing 11). The tab 13a has a slit 13b. On the other hand, the jig 13 has at its rear extremity a cam engaging piece 13c (see Fig. 3) bent upward from the marginal edge of the rear end portion of the jig (lying within the housing 11). Though not shown in Figs. 2 and 3, the tab 13a has made therein a cutter receiving concavity in opposing relation to the cutter receiving recess 12 (see Figs. 4 and 5).

[0076] A jig operating lever 14 is pivotally secured to the housing 11 of the controller 10. To a rotary shaft of the operating lever 14 is coupled a cam 15. The cam 15 is in engagement with a cam engaging piece 13c of the rear end portion of the jig 13. Interengagement of the cam 15 and the cam engaging piece 13c allows back-and-forth motion of the jig 13 by manipulation of the operating lever 14.

[0077] Turning next to Figs. 4 to 7, the initial treatment rotating cutter 3 and the secondary treatment rotating cutter 7 will be described in detail.

[0078] Fig. 4 is a perspective view showing the rotating cutter of the medical instrument according to the first embodiment of the present invention.

[0079] Fig. 5 is a radially sectioned elevational view partially showing the cutting surface of the rotating cutter of Fig. 4.

[0080] Fig. 6 is its axially sectioned elevational view of Fig.5.

[0081] Fig. 7(A) is a perspective view showing the initial treatment rotating cutter and the secondary treatment rotating cutter in their yet-to-be coupled state, and Fig. 7(B) a perspective view showing the both cutters of Fig. 7(A) in their coupled configuration.

[0082] The illustrated initial treatment rotating cutter 3 has in its surface a large number of microscopic cutting edges 300. These cutting edges 300 are formed integrally with a cutter mother material in appropriately spaced-apart and individually independent relation. On the other hand, the secondary treatment rotating cutter 7 also has in its surface a great number of microscopic cutting edges 700. These cutting edges 700 are also formed integrally with a cutter mother material in appropriately spaced-apart and individually independent relation. As depicted in Fig. 5, the cutting edges 300 and 700 are composed of microscopic concavities 301, 701 and microscopic convexities 302, 702 formed in the surfaces of the both cutters 3 and 7.

[0083] More specifically, the concavities 301 and 701 consist of elongated grooves extending in the direction of rotation of the cutters 3 and 7. The elongated grooves 301 and 701 are configured such that they extend in the direction of rotation of the cutters 3 and 7, gradually get deeper rearwardly in the direction of rotation and terminate at the deepest point at which the grooves rise steeply. On the other hand, the convexities 302 and 702 form bump-like cutting edges that extend upright from the deepest point of the elongated grooves 301 and 701 and jut out of the cutter surfaces. These cutting edges 302 and 307 are circular in section as viewed in the direction of rotation of cutters 3 and 7 (refer to Fig. 6). Besides, back walls 303 and 703 are formed, which gradually tail off from the marginal edges of their upstanding end faces of the cutting edges (the convexities) 302 and 702 in a direction opposite the direction of rotation of the cutters.

[0084] The widths W of the elongated grooves 301, 701 and the cutting edges 302, 702 and the heights H of the cutting edges 302, 702 relative to the cutter surface are chosen such that chippings of deposits removed from the narrowed vascular portion by high-speed rotation of the cutters are 10 microns at largest in size.

[0085] Next, a description will be given of removal of deposits from the narrowed vascular portion 2 by use of the medical instrument according to the first embodiment.

[0086] The initial treatment begins with inserting the guide wire 1 into a blood vessel until the distal end of the guide wire 1 passes through the narrowed vascular portion 2. This is followed by navigating the initial treatment rotating cutter 3 over the guide wire 1 to the narrowed vascular portion 2 while rotating the cutter at low speed. At the instant the rotating cutter 3 reaches the narrowed vascular portion 2, the cutter 3 is switched to high-speed rotation. And deposits in the narrowed vascular portion 2 are removed by the large number of microscopic cutting edges 300 of the rotating cutter 3 for initial treatment.

[0087] In the case of performing treatment for further distending the narrowed vessel 2 in succession to the initial treatment, the rotating cutter 3 is once drawn out over the guide wire 1 from a patient's body together with the drive shaft 4 and the sheath 5 while at the same time leaving the wire 1 within the patient's body (in the blood vessel). Without being taken off the guide wire 1, the rotating cutter 3 thus pulled out of the patient's body is fitted into the secondary treatment rotating cutter 7 held in the cutter receiving concavity 12 of the controller 10 as shown in Fig. 2.

[0088] Following this, the jig 13 is moved toward the housing 11 by means of the jig operating lever 14. By this, the initial treatment rotating cutter 3 is pressed into the secondary treatment rotating cutter 7. The both cutters 3 and 7 are combined into such a unitary structure as if the diameter of the initial treatment rotating cutter 3 is enlarged by the secondary treatment rotating cutter 7.

[0089] After coupling the both cutters 3 and 7 into a one-piece structure as mentioned above, the jig 13 is opened, from which the combined cutters 3 and 7 (a unit cutter) are removed and shifted over the guide wire 1 toward the patient side forwardly of the front-end tab 13a of the jig 13. Following this, the unit cutter, driven at low speed, is inserted into the blood vessel and navigated over the guide wire 1 remaining within the vessel to the initially treated narrowed vascular portion 2. And the unit cutter is rotated at high speed to remove the deposits remaining in the narrowed vascular portion by the number of microscopic cutting edges 700 (by the cutting edges 702, in particular).

[0090] According to the first embodiment described above, during initial removal of deposits from the narrowed vascular portion 2 by the initial treatment and during subsequent treatment for

distending the narrowed vascular portion by the unit cutter composed of the both rotating cutters 3 and 7, there is no such possibility of diamond abrasive grains coming off as is the case with the conventional cutting bar; hence, the affected area can be treated efficiently and safely by cutting. In addition, since the convexities 302 and 702 of the microscopic cutting edges 300 and 700 of the both cutters 3 and 7 are sufficiently small and appropriately spaced apart, there is little likelihood of the cutting edges 302 and 702 being deformed by a cutting reaction force. This ensures generation of sufficient cutting force.

[0091] With the medical instrument according to the first embodiment, since chippings of deposits removed from the narrowed vascular portion by the cutters 3 and 7 are held in sizes of 10 microns and less by choosing dimensions of the elongated grooves 301, 301 and convexities 302, 702 of the microscopic cutting edges 300 and 700 precluding the possibility of blocking peripheral blood vessels by chippings of deposits removed from the affected area.

[0092] With the medical instrument of the first embodiment, since the microscopic cutting edges 300 and 700 are sufficiently small and properly spaced apart, even if the both cutters 3 and 7 are joined together, the juncture of their cutting surfaces (microscopic cutting edges 300 and 700) is smooth. In addition, since the microscopic cutting edges 300 and 700 can be distributed over the entire areas of the cutters 3 and 7 even along their marginal edges, the microscopic cutting edges 300 and 700 can be formed as well in close proximity of the surface of junction of the cutting surfaces of the both cutters 3 and 7. This ensures prevention of undue discontinuities of the microscopic cutting edges 300 and 700 between the both cutters 3 and 7.

[0093] With the medical instrument according to the first embodiment, in the case of treating again for further distending the narrowed vascular portion 2 after the initial treatment, there is no need for replacing the rotating cutter 3 with a new one after completely pulling out all of the controller 10, the rotating cutter 3, the drive shaft 4 and the fixed sheath 5 from the patient's body as in the prior art. With the medical instrument according to the first embodiment, the diameter of the cutting surface can readily be enlarged by merely engaging the secondary treatment rotating cutter 7 with the rotating cutter 3 on the guide wire 1 extending out of the patient's body. Hence, step-by-step cutting treatment of the narrowed vascular portion can be performed promptly and efficiently.

[0094] Fig. 8 is a sectional view showing a part of a rotating cutter of a medical instrument according to a second embodiment of the present invention.

[0095] In the rotating cutters 3 and 7 in the second embodiment, the areas where cutting surfaces by pluralities of microscopic asperities forming the microscopic cutting edges 300 and 700 are located in overlapping relation with one another.

[0096] According to such rotating cutters 3 and 7, their microscopic cutting edges 300 and 700 form individually independent but closely packed cutting structures on the surfaces of the rotating cutter 3 and 7. This permits reduction in the amount of narrowing material left unremoved in the affected area.

[0097] Fig. 9 illustrates, by way of example, working for forming the microscopic cutting edges of the rotating cutter of the medical instrument according to the present invention.

[0098] Fig. 9(A) shows an example of working for forming the microscopic cutting edges 300 of the initial treatment rotating cutter 3. The rotating cutter 3 is shown to be chucked at a chuck pawl 100 around its rear outer periphery (the outer periphery of the large-diameter side). A center fixing shaft 101 is pressed against the tip end of the rotating cutter 3 on the small-diameter side axially thereof. And the outer peripheral surface of the rotating cutter 3 is cut out by a diamond needle 102 to form the microscopic cutting edges 300. That is, the microscopic cutting edges 300 are formed by piercing the diamond needle 102 into the mother material surface of the rotating cutter down to a predetermined depth.

[0099] Fig. 9(B) shows an example of working for forming the microscopic cutting edges 700 of the secondary treatment rotating cutter 7. In this drawing, the ring-shaped rotating cutter 7 is shown to be fitted at one end into a male-female holder shaft 103. The other end portion of the rotating cutter 7 is fixed to a fixing screw 104. In this case, too, the microscopic cutting edges 700 is formed by piercing the diamond needle 102 into the mother material surface of the rotating cutter 7 as is the case with Fig. 9(A).

[00100] With such a method, it is possible to easily form properly spaced-apart, independent microscopic cutting edges 300 and 700 in the respective surfaces of the cutter 3 and 8.

[00101] While in the above the method for forming the convexities by plastic working has been described in connection with Fig. 9, it is also possible to employ other convexities forming methods such as laser machining, electric discharge machining, etching, press work, pressure welding and cutting work. In the laser or electric discharge machining, rims are formed about points of working on the cutting surface just like craters without transpiring the material being worked. In the etching machining, for example, abrasive grains are coated discretely all over the cutting surface, after which the cutting surface is etched away around the grains to leave their underside portions as convexities. In the press or cutting work, the cutting surface is cut out to form burrs as convexities. In the pressure welding, abrasive grains are crushed on the cutting surface so that they stick thereto as convexities.

[00102] Fig. 10 shows partly in section, the cutting structure of the rotating cutter of a medical instrument according to a fourth embodiment of the present invention.

[00103] The rotating cutter 3 of the fourth embodiment is so formed as to undergo plastic deformation, and has in its surface a number of individually independent, properly spaced-apart microscopic cutting edges 300. To perform initial treatment of the narrowed vascular portion, the rotating cutter 3 is used in a non-plastically deformed configuration shown in Fig. 10(A). And, in the case of further distending the narrowed vascular portion after the initial treatment, the rotating cutter is compressed axially to undergo plastic deformation in a radial direction in which to enlarge its diameter as depicted in Fig. 10(B).

[00104] The rotating cutter 3 of the fourth embodiment permits reduction in the cutting reaction force that is applied to the surface of the cutter 3 during cutting treatment of the affected area. The reason for this is that the diamond cutting edges shown in Fig. 15 are oriented differently with respect to one another, and hence diamond grains pointed in a certain direction act as cutting edges but in other directions they are obtrusive protrusions that merely increase friction. On the other hand, since the cutting edges in this embodiment are oriented only in the cutting direction as shown in Fig. 5, the cutting reaction force is small. Moreover, the concavities surrounding the convexities act as friction surfaces during cutting, but by forming them as mirror-finished surfaces, the cutting reaction force can be reduced. Further, the cutting edges may wear after cutting, but this can be avoided by, for example, coating the cutting surface

with a hard plated layer as depicted in Fig. 9. Such reduction of the cutting reaction force permits reduction in the thickness of the rotating cutter 3; hence, plastic deformation of the rotating cutter 3 for enlargement of its diameter will not cause cracking in the microscopic cutting edges 300 or lead to deformation of the microscopic cutting edges 300. Accordingly, the lowering of the cutting performance can be suppressed.

[00105] Fig. 11 illustrates, in a partially sectioned side elevation, a jig for enlarging the diameter of the rotating cutter of a medical instrument according to a fifth embodiment of the present invention.

[00106] A jig 16 shown in Fig. 11 has a one-hand operated lever mechanism. The jig 16 includes a pair of operating levers 16A and 16B pivotally interconnected by a pin P. The one operating lever 16A has at its upper extremity a cutter receiving seat 17 formed unitary therewith. In the cutter receiving seat 17 there are formed an aperture 17a, a cutter receiving concavity 17b for fitting and retaining therein the secondary rotating cutter 7, and a slit 17c for fitting therein the fixed sheath 5.

[00107] Through the aperture 17a of the cutter receiving seat 17 there is slidably inserted a press member 18. The press member 18 is substantially L-shaped in cross section, and has an engaging piece 18a for engagement with the upper extremity of the other operating lever 16B. The press member 18 has made therein a cutter receiving concavity 18b for receiving the initial treatment rotating cutter 3 and a slit 18c for receiving the guide wire 1.

[00108] In the case of using the jig according to the fifth embodiment, as shown in Fig. 11(A), the secondary treatment rotating cutter 7 is engaged and held in the cutter receiving concavity 17b of the cutter receiving seat 17 in advance, whereas the initial treatment rotating cutter 3 is engaged in the cutter receiving concavity 18b of the press member 18 in advance, too. the operating levers 16A and 16B squeezed, the intermediate shoulder 3b of the initial treatment rotating cutter 3 is pressed into the annular secondary treatment rotating cutter 7. By this, the both cutters 3 and 7 are combined into a unitary structure as shown in Fig. 11(B) to provide an enlarged-diameter cutting surface.

[00109] Fig. 12 is a sectioned side elevational view illustrating the construction of a

controller of a medical instrument according to a fifth embodiment of the present invention.

[00110] Fig. 13 is an enlarged sectioned side elevational view illustrating the construction of the essential part of the controller of the medial instrument shown in Fig. 12.

[00111] Fig. 14 is a sectioned side elevational view showing the controller of the Fig. 12 medical instrument, with a sheath connector taken away.

[00112] As depicted in Fig. 12, the controller 10 has a housing 11. The housing 11 has a grip 11A integrally extending therefrom upwardly. The grip 11A has attached thereto a grip lever 30. The grip lever 30 has built therein a lever core bar 31, and the lever core bar 31 is pivotally mounted by a pin P1 on the grip 11A.

[00113] A lock lever 32 is connected to the pin P1. To a lower end portion 31a of the lever core bar 31 in the housing 11 is attached a motor holder 33 below the pin P1. In a mounting piece for mounting the motor holder 33 on the lever core bar 31 there is formed a guide slit 34. A guide pin 35 extending from the lower end portion of the lever core bar 31 is slidably received in the guide slit 34. The motor holder 33 holds therein a motor 36. On the output shaft of the motor 36 is fitted an eccentric cam 37. In the outer periphery of the eccentric cam 37 is fitted a bearing holder 39 through bearings 38. The bearing holder 39 has a depending shaft 39a integrally extending from the underside of the holder centrally thereof.

[00114] In the housing 11 there is placed a cylindrical slider 40. The slider 40 is connected to the depending shaft 39a so that it can reciprocate axially of the drive shaft 4. The slider 40 is biased by a spring 41 in a direction of retraction (a direction in which to pull out the drive shaft 4 from the patient's body). In the inner periphery of the slider 40 there is disposed an armature core 42. Inside the armature core 42 is disposed a rotor magnet 44 through an armature coil 43. The slider 40 has built therein a Hall sensor 45. The slider 40, the armature core 42, the armature coil 43, the rotor magnet 44 and the Hall sensor 45 constitute a drive shaft rotating brushless motor assembly 46 in the housing 11.

[00115] Inside the rotor magnet 44 there is rotatably disposed a sleeve-like hollow rotary shaft 47. A sleeve-like chuck member 48 is axially movably inserted in the hollow rotary shaft 47. The chuck member 48 has at one end (front end) in its axial direction a chuck pawl 48a

integrally formed therewith for chucking the drive shaft 4. On engaging with one end of the hollow rotary shaft 47 in its axial direction, the chuck pawl 48a contracts diametrically to chuck the drive shaft 4. Shifting in a direction to disengage from the one end of the hollow rotary shaft 47, the chuck pawl releases the drive shaft 4. To the other end (the terminal end) of the chuck member 48 in its axial direction is threadably attached a chuck connecting member 49. The chuck member 48 and the chuck connecting member 49 are biased by a spring 50 in a direction in which the chuck pawl 48a chucks the drive shaft 4. With such an arrangement, the hollow rotary shaft 47, the chuck member 48, the chuck pawl connecting member 49 and the spring 50 constitute a drive shaft 4 chucking mechanism. Incidentally, the chuck member 48 and the chuck connecting member 49 need only to be configured as a single sleeve that has the chuck pawl 48a formed integrally therewith at one end in the axial direction and allows the insertion therethrough of the drive shaft 4.

[00116] In the rear of the chuck pawl connecting member 49 is situated a cylinder knob 51 for chucking release use. The cylinder knob 51 is held by a cylinder holder 52 in the housing 11 so that it is axially shiftable to abut against the rear end of the chuck pawl connecting member 49. The cylinder knob 51 is biased by a spring 53 in a direction away from the chuck pawl connecting member 49.

[00117] To the front end of the housing 11 a sheath connector 54 is detachably secured about the drive shaft 4. The sheath connector 54 has fitted thereon the soft fixed sheath 5. The sheath connector 54 has pressed therein a mechanical seal 55, and the mechanical seal 55 makes sliding contact with the drive shaft 4. A physiological salt solution supply tube 56 communicates with the sheath connector 54.

[00118] Next, a description will be given of the operation of the controller 10.

[00119] After the rotating cutter 3 has been navigated over the guide wire 1 to the narrowed vascular portion 2 as shown in Fig. 1, the brushless motor 46 for driving the drive shaft is brought into operation. Then the drive shaft 4, the chuck pawl 48a chucking the drive shaft 4 and the chuck pawl connecting member 49 coupled to the rear end of the chuck member 48 rotate as a unit with the rotor magnet 44. By this, the rotating cutter 3 at the distal end of the drive shaft 4 rotates to remove deposits from the narrowed vascular portion 2.

[00120] Putting the motor 36 into operation during rotation of the rotating cutter 3, the eccentric cam 37 rotates and the bearing holder 39 also rotates eccentrically as a unit with the eccentric cam 37. Then the slider 40 connected to the depending shaft 39a of the bearing holder 39 reciprocates axially thereof. As a result, the drive shaft 4 reciprocates axially thereof through the drive shaft driving motor assembly 46 provided unitary with the slider 40 and the chuck member 48. Accordingly, the rotating cutter 3 at the extreme end of the drive shaft 4 is imparted a rotary motion as well as a reciprocating motion along the guide wire 1 ensuring increasing or stabilizing the cutting force of the rotating cutter 3 for removing deposits in the narrowed vascular portion 2.

[00121] In the case of treating the narrowed vascular portion 2 for further distending the vessel after initial treatment of the narrowed vascular portion 2 by the rotating cutter 3, the rotating cutter 3 and the drive shaft 4 are once pulled out along the guide wire 1 from the patient's body. At this time, the drive shaft 4 is released from chucking by the chuck pawl 48a. In this case, pushing cylinder knob 51 for chucking release use against the spring 53, the chuck pawl connecting member 49 and chuck member 48 are pushed forward by the cylinder knob 51 against the spring 50, and the chuck pawl 48a moves forwardly of the front end of the hollow rotary shaft 47 and opens. Thus the drive shaft 4 is released from chucking by the chuck pawl 48a, and hence the drive shaft 4 can be easily pulled out along the guide wire 1 from the patient's body.

[00122] During removal of deposits from the narrowed vascular portion 2 by the rotating cutter 3 or by the secondary treatment rotating cutter 7 mounted on the rotating cutter 3 as a unitary structure therewith, a physiological salt solution is supplied from the tube 56 into the sheath connector 54. The physiological salt solution flows through the fixed sheath 5 and gushes out toward the rotating cutter 3.

[00123] According to this method, since the mechanical driving assembly for the controller 10 is formed by a combination of the motor 36 provided with the eccentric cam 37 for vibrating use and the brushless motor 46 for drive shaft rotating use, it is possible to impart combined cutting forces by rotary and reciprocating motions to the rotating cutter 3. This ensures increasing or stabilizing the cutting force of the rotating cutter 3 for removing deposits

from the narrowed vascular portion 2. Further, the rotating cutter 3 and the sheath 5 can be easily inserted into the guiding catheter 6 with less friction.

INDUSTRIAL APPLICABILITY

[00124] As is apparent from the description given above, the present invention precludes the possibility of diamond abrasive grains falling off the cutting bar as in the prior art during removal of deposits from a narrowed vascular portion, and hence the invention permits efficient and safe cutting treatment of the affected area of the patient's body; moreover, in the case of further distending the narrowed vascular portion after initial treatment, the invention eliminates the need for replacing the rotating cutter after removing the rotating cutter and the controller in their entirety from the guide wire prompting distention of the narrowed vascular portion.